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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 07/164,683  | 09/11/2000  | Rajnikant Patel      | 07164.0004-02       | 9148             |
| ZENECA PHARMACEUTICALS LP<br>MEDICAL INTELLECTUAL PROPERTY<br>100 CONCORD PIKE<br>WILMINGTON, DE 19850-5437 |             |                      |                     |                  |
| EXAMINER<br>WRIGHT, SONYA N   |             |                      |                     |                  |
| ART UNIT<br>1626  |             | PAPER NUMBER         |                     |                  |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/659,683 | <b>Applicant(s)</b><br>PATEL, RAJNIKANT |  |
|                              | <b>Examiner</b><br>Sonya Wright      | <b>Art Unit</b><br>1626                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

### **DETAILED ACTION**

This is in response to Applicants amendment filed January 20, 2004. Claims 1-12 and 14-26 have been canceled. Claim 27 has been added. Claims 13 and 27 are pending in this application. The rejection under 35 U.S.C. 102 has been maintained.

#### ***Election/Restrictions***

Claim 27 is drawn to a "compound" prepared by a process comprising steps a), b), c), and d). However, Applicant has not indicated what "compound" is prepared by the process of claim 27. The "compound" prepared in claim 27 has not been limited to non-solvated, pure (S)-4-[[3-[2-(dimethylamino)ethyl-1H-indole-5-yl]methyl]-2-oxazolidinone, the compound of claim 13. Therefore, claim 27 contains divergent subject matter which would require a different search and examination. Claim 27 has therefore been withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 102***

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Robertson et al., US Patent 5,399,574. Applicant claims (S)-4-[[3-[2-(dimethylamino)ethyl-1H-indole-5-yl]methyl]-2-oxazolidinone. On page 1 of the specification Applicant discloses that this compound is also known as (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidin-4-yl)-methyl]-1H-indol-3-yl]ethylamine, and that it is useful for the treatment of migraine.

Robertson et al. teach the instant compound in species examples in column 28, lines 21-22 and lines 44-45, and column 29, lines 6-7. Robertson et al. also teach that their compound is useful in the treatment of migraine in column 1, line 8.

The examiner assumes that the compound of Robertson et al. is non-solvated and pure absent a showing to the contrary. A compound, by default, if not explicitly named to have solvent, is a non-solvated compound. Please note column 28, lines 29-32, where the disclosure indicates the non-solvated nature of the compounds of Robertson et al.. Column 28, lines 29-32 describes that a solid was suspended in HCL aq., refluxed, diluted with water and filtered. "The classic definition of purity is that a sample of a chemical compound is pure when it contains molecules of only one kind" (see Physics and Chemistry of the Organic Solid State Sloan, p. 181, lines 4-6, attached). Based on this definition, the disclosure of Robertson et al., in column 28, lines 29-32 meets the "pure" requirement of the claim. Additionally, at column 29, lines 15-18, the compound has been further purified to a level of NMR pure. Therefore, every element of the claim is met and anticipation is found.

### ***Response to Arguments***

Applicant's arguments filed January 20, 2004 have been fully considered but they are not persuasive.

Applicant argues that the Examiner has not shown a pure, non-solvated form of the compound in any reference. Applicant argues that the Examiner does not refer to any language in Robertson et al. to show that the compound is in a pure, non-solvated form. Applicant argues that there is nothing recited in the process steps to indicate that

Robertson et al. sought to attain a pure and non-solvated form of the compound.

Applicant argues that the Examiner shows no teaching that the NMR sample at Column 20, lines 15-18 is pure. Applicant argues that the Examiner does not refer to any reference, document, teaching or facts within her own knowledge that show that when one lists a compound, by just naming it, teaches a non-solvated form.

However, in Applicant's specification, on page 1, lines 20 and 21, Applicant admits that Robertson describes the compound (S)-4-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-2-oxazolidinone in WO91/18897, which is the international application published under PCT that relates to US Patent 5,399,574. In addition to teaching the compound, Robertson et al. in fact teach the non-solvated nature of the compounds in column 28, lines 29-32, wherein Robertson et al. teach purification of a solid wherein a solid was suspended in HCl aq., refluxed, diluted with water and filtered. Further, the compounds of Robertson et al. meet the definition of "pure" given in Physics and Chemistry of the Organic Solid State Sloan, p.181, lines 4-6 which is that the compound contains "molecules of only one kind". At column 29, lines 15-18, the compound of Robertson et al. has been further purified to a level of NMR pure, meaning that the compound is pure enough to be analyzed using NMR.

Applicant has provided only general guidance in the specification regarding what is meant by "non-solvated" or "pure". Applicant gives only general information regarding the non-solvated and pure compound on page 9, by stating on page 9, line 23 that "the resulting product is a non-solvated solid of high purity". Applicant has not shown experimental evidence to support Applicant's position that the instant compound

is patentable over the compound of Robertson et al. Therefore, every element of the claim is met and anticipation is found.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Kamal Saeed  
for Joseph K. McKane  
Supervisory Patent Examiner  
Group 1600

Sonya Wright

March 5, 2004